



# UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE  
United States Patent and Trademark Office  
Address: COMMISSIONER FOR PATENTS  
P.O. Box 1450  
Alexandria, Virginia 22313-1450  
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/654,761	09/04/2003	Dennis Ausiello	17509-0065	6913
29052	7590	11/16/2005	EXAMINER	
SUTHERLAND ASBILL & BRENNAN LLP			HAN, MARK K	
999 PEACHTREE STREET, N.E.			ART UNIT	
ATLANTA, GA 30309			PAPER NUMBER	
			3767	

DATE MAILED: 11/16/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/654,761

Applicant(s)

AUSIELLO ET AL.

Examiner

Mark K. Han

Art Unit

3767

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 August 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-10, 12-27, 29 and 32-35 is/are rejected.
- 7) ☒ Claim(s) 11, 28, 30 and 31 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 04 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>see continuation</u> . | 6) <input type="checkbox"/> Other: _____  |

Continuation of Attachment(s) 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s) Mail Date: 23  
February 2004, 26 April 2004, 09 August 2004

## DETAILED ACTION

### *Election/Restrictions*

1. Applicant's arguments, see pp. 2-3, filed 19 August 2005, with respect to the restriction/election of species requirement have been fully considered and are persuasive. The restriction/election of species requirement has been withdrawn.

### *Claim Rejections - 35 USC § 103*

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 1-10, 12-18, 22-27, 29 and 32-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,797,898 to Santini, Jr. et al. (hereinafter "Santini") in view of Rubin, et al., "The Potential of Parathyroid Hormone as a Therapy for Osteoporosis," *Int. J. Fertil.* 47(3): 103-15 (2002) (cited by applicants; hereinafter "Rubin").

Santini discloses an implantable device having a substrate, plurality of reservoirs, a release system, control means, sensor and reservoir caps. See Figures 1-7c. Santini suggests that hormones may be used in the release system but does not specifically employ parathyroid hormone. See col. 5, lines 12-18. Rubin suggests the use of parathyroid hormone to treat osteoporosis. Rubin discusses dosage, length of therapy and the use of bone resorption inhibitors as well. It would have been obvious to one of ordinary skill in the art to modify the system

Art Unit: 3767

disclosed by Santini, by including parathyroid hormone as the release system in order to provide therapy for those suffering from osteoporosis.

3. Claims 19 and 20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Santini and Rubin, further in view of U.S. Patent No. 6,264,990 to Knepp et al. (hereinafter "Knepp").

Santini and Rubin disclose the claimed invention as shown above except for the parathyroid hormone in a lyophilized form. Knepp discloses a way to lyophilize parathyroid hormone with an excipient. See col. 4, lines 4-10. It would have been obvious to one of ordinary skill in the art to modify the invention of Santini and Rubin by including a lyophilized form of parathyroid hormone in order to enhance the shelf life of the drug.

4. Claim 21 is rejected under 35 U.S.C. 103(a) as being unpatentable over Santini and Ruben, further in view of U.S. Patent No. 6,011,011 to Hageman.

Santini and Rubin disclose the claimed invention as shown above except for an excipient of polyethylene glycol. Hageman teaches the use of polyethylene glycol as an excipient with parathyroid hormone. See col. 3, line 28 through col. 4, line 12. It would have been obvious to one of ordinary skill in the art to modify the invention of Santini and Rubin by including polyethylene glycol as an excipient in order to provide a sustained or prolonged release of the hormone.

#### *Allowable Subject Matter*

5. Claims 11, 28, 30 and 31 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

*Contact Information*

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark K. Han whose telephone number is 571-272-4958. The examiner can normally be reached on Monday to Friday, 9 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on 571-272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mark K. Han  
Patent Examiner  
Art Unit 3767

mkh  
November 14, 2005

**KEVIN C. SIRMONS**  
**PRIMARY EXAMINER**

